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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,688	04/16/2008	Mark L. Greene	UPN-5231	9908

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,688	GREENE ET AL.	
	Examiner	Art Unit	
	SAMUEL LIU	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1-8 and 13, drawn to a multimeric peptidomimetic comprising plural monomers that comprise exocyclic peptide, a linker and a motif required for forming the multimer, and a process of producing (claim 13) a multimeric peptidomimetic using the monomer.

Group 2, claims 9-11, drawn to a nucleic acid encoding the monomer that comprises the exocyclic peptide having a ring structure, a linker and a motif required for forming a multimer, a expression vector comprising the nucleic acid and a host comprising the vector.

Group 3, claim 12, drawn to a method of delivering a drug to a cell comprising contacting the cell with the multimeric peptidomimetic of Group 1.

Group 4, claim 12, drawn to a method of a toxin to a cell comprising contacting the cell with the multimeric peptidomimetic of Group 1.

Group 5, claim 12, drawn to a method of delivering a nucleic acid to a cell comprising contacting the cell with the multimeric peptidomimetic of Group 1.

Group 6, claim 12, drawn to a method of delivering a radionuclide to a cell comprising contacting the cell with the multimeric peptidomimetic of Group 1.

Group 7, claim 12, drawn to a method of a detectable compound to a cell comprising contacting the cell with the multimeric peptidomimetic of Group 1.

Group 8, claim 14-23, drawn to a purified recombinant protein comprising a cell binding domain and a biotin-binding streptavidin core sequence wherein said cell binding domain contains an active domain of a heterologous polypeptide, and a tetrameric protein complex comprising the protein thereof.

Group 9, claim 24, drawn to a method of delivering a drug to a cell comprising contacting with a tetrameric protein of Group 8.

Group 10, claim 25, drawn to a process of using the protein of Group 8 to produce a tetrameric protein.

The inventions listed as Groups 1-10 do not related to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The nucleic acid of Group 2, the protein of Group 8 and the peptidedomimetic of Group 1 comprising the exocyclic peptide of Group I are distinct/different in the structure from one another. In the instant case, the nucleic acid claims do not overlap the scope of the polypeptide claims and vice versa as evidenced by the distinct structures and functions of the claimed inventions. A structure of nucleic acid is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure. Additionally, the nucleic acid and polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. The peptidomimetic of Group 1 differs from the protein of Group 8 in that the cell binding domain and the biotin-biding streptavidin core sequence are absent in the peptidomimetic molecule, while exocyclic peptide of Group 1 may not necessarily present in the protein of Group 8. The patentable distinctness between product/composition Groups 1, 2 and 8 render the processes (Groups 3-7, 9 and 10) using said product/composition of said Group 1, 2 or 8 distinct from one another. Thus, there is no claim(s) that constitutes a special technical feature linking all claims, as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

Additional Election

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed biomolecule to which claims are restricted. The response to the election requirement should also identify the claims readable thereon as directed to the elected invention.

If Group 8 is elected, applicants are required to elect;

(i) one heterologous polypeptide from claim 15 because antibodies and antigens or ligand for cell surface receptor are structurally and functionally distinct/different from one another; and

(ii) one protein bound to said heterologous polypeptide from claim 16, because the proteins set forth in the claims such as IL-3 and EGFR are distinct in amino acid sequence and biological function; and

(iii) one particular type molecule from claim 22 wherein the molecule is bound to the streptavidin core sequence in the recombinant protein, and wherein said molecule is a biotinylated drug, a biotinylated toxin, a biotinylated nucleic acid molecule, a biotinylated radionuclide or a biotinylated detectable compound, becasue these molecules such as nucleic acid and toxin (such as ricin toxin which is a glycoprotein, see page 14, line 9, instant specification) are distinct from one another in chemical structure and in biological function.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 US 121, since the above-mentioned molecules subjected to "additional election" (such as "antibodies" versus the "ligand for cell surface receptor", and the "nucleic acid" versus the "protein") are distinct/different from one another in structure (amino acid sequence and/or chemical structure resulted from post-translational modification) and function (biological activity).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Liu whose telephone number is (571)272-0949. The examiner can normally be reached on Monday-Friday, 9 am to 5:30 pro. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Wei Liu/
Patent Examiner, Art Unit 1656
/ANAND U DESAI/
Primary Examiner, Art Unit 1656
May 5, 2010